

REMARKS

Claims 25, 27-43, 45, 47 and 48 are pending.

New Claim

Claim 48 is new and is supported throughout the specification, including by paragraph 17 of the published specification (U.S. Publication Number 2004/0198813A1). No new matter is added in claim 48.

Amendments to the Claims

The amendments to claims 25 and 45 are supported, *inter alia*, by the specification at paragraph 83 of the published specification. The claims are amended to speed up prosecution and without prejudice or disclaimer of the original subject matter claimed therein. No new matter is added by way of these amendments. The applicants reserve the right to pursue any cancelled subject matter in at a later time.

Rejections under 35 U.S.C. §103(a)

Claims 25, 27-30, 34, 37-38, 40-41, 43 and 47 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. 6024978 ("Hauer") as evidenced by The Merck Index (1989). Applicants respectfully disagree but have nevertheless amended the claims to speed up prosecution. Applicants respectfully submit that this rejection is moot in view of the amendments to the claims.

The office action cites Example 5.2 of Hauer as disclosing a thickened "emulsion pre-concentrate" comprising cyclosporin, Pluronic F68 and sodium laurylsulphate. The applicants respectfully submit that the formulation described in this example also includes Transcutol. Hauer teaches a

microemulsion pre-concentrate including a hydrophilic phase, a lipophilic phase and a surfactant (column 6, lines 30-50.) Transcutol is taught as being a component of the lipophilic phase (column 7, lines 14-50), which acts as a carrier for cyclosporin and enables cyclosporin loading of the composition that is adequate for convenient therapeutic dosaging (column 8, lines 9-16.)

Applicants respectfully submit that Hauer does not teach or suggest microemulsion pre-concentrates that do not include a carrier, such as Transcutinol. Furthermore, because Hauer teaches that such a carrier is present to obtain sufficient cyclosporine loading, Hauer would not give those skilled in the art any reason to prepare a microemulsion that does not include such a carrier. In view of the amendments and arguments presented above, the applicants respectfully request that the rejection of claims 25, 27-30, 34, 37-39, 40-41, 43 and 47 under 35 U.S.C § 103(a) be withdrawn.

Claims 33-33, 39 and 45 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Hauer in view of WO 9408610 ("Constantinides".) Applicants have discussed Hauer above and respectfully submit that Constantinides does not make up for the deficiencies of Hauer. Constantinides teaches emulsions including an oil and a water soluble biologically active agent (page 5, lines 9-17.) Constantinides does not teach or suggest an emulsion having an oil phase including an oil-soluble drug in the absence of separate carrier of the drug. Applicants respectfully request that the rejection of claims 31-33, 39 and 45 under 35 U.S.C § 103(a) be withdrawn.

Claims 34-36 and 42 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Hauer as evidenced by The Merck Index (1989, page 1364) in view of The Merck Index (1989, page 478).

Applicants have discussed Hauer above and respectfully submit that they have addressed the deficiencies of this reference. Applicants

respectfully request that the rejection of claims 34-36, 39 and 42 under 35 U.S.C § 103(a) be withdrawn.

Applicants submit that the claims are now in condition for allowance. If, for any reason, the Examiner is unable to allow the application and wishes to resolve any remaining issues, she is respectfully requested to contact the undersigned attorney at (312) 321-4229.

Respectfully submitted,

Dated: July 7, 2009

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